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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,483	08/17/2001	Katalin Veronika Lukacs	12071-010002	5360

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EXAMINER

EWOLDT, GERALD R

ART UNIT PAPER NUMBER

1644

DATE MAILED: 02/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.	Applicant(s)	
09/932,483	LUKACS ET AL.	
Examiner	Art Unit	
G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 24 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9, 11-33, 39 and 40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-33, 39 and 40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/17/01</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Applicant's election with traverse of the species: A) allergic airway diseases, B) HSP-60 family heat shock proteins, and C) the parameters of Claim 24, i.e., improvement in a mammal's PC<sub>20</sub>methacholine FEV<sub>1</sub> value, filed 10/24/03, are acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the species restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 1-9, 11-33, and 39-40 are being acted upon.
3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:  
A person shall be entitled to a patent unless --  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
4. Claims 1-9, 11-14, 16-27, 32-33, and 39-40 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 92/08488 (1992, IDS).

WO 92/08488 teaches a method to protect a mammal from a disease characterized by eosinophilia (allergic airway disease, i.e., asthma) associated with an inflammatory response, said method comprising administering a heat shock protein (mycobacterial HSP 65) to a mammal having said disease, by a parenteral route, wherein said disease is associated with increased production of a cytokine selected from the group consisting of IL-4, IL-5, or IL-10. The reference additionally teaches that administration of the heat shock protein induces IFN- $\gamma$  production by T cells (i.e., TH1 cytokines) and decreases IL-4, IL-5, or IL-10 production (i.e., TH2 cytokines) (see particularly, columns 1 and 2). Note that Claims 16-19 recite limitations comprising a reduction of eosinophil blood counts and Claims 22-27 recite limitations comprising decreases in methacholine responsiveness. These limitations comprise only characteristics of an increased TH1 response and a decreased TH2 response and are inherent to the administration of a composition (i.e., a HSP) that increases a TH1 response and decreases a TH2 response.

The reference clearly anticipates the claimed invention.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 15, 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 92/08488 (1992, IDS).


WO 92/08488 has been described above. The reference teaching differs from the claimed invention only in that it does not teach an oral or nasal route of administration nor the dosage ranges of Claims 28-31. Regarding the routes and dosages of administration, the choice of said routes and dosages comprises only routine optimization of the claimed method, said routine optimization falling well within the purview of one of skill in the art at the time of the invention.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

**Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Primary Examiner  
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2/9/04  
**G.R. EWOLDT, PH.D.**  
**PRIMARY EXAMINER**